

### **REMARKS**

Claim 1 has been amended to recite that the composition is not administered with estrogen. Support resides in the specification, paragraph [0012] and in Examples 1 through 8. Claims 16-20 have been added. Support for the new claims resides in the previous claims, in the specification, and Examples 1-8. Specifically, claims 16 and 17 recite gender as described in the Examples. Claim 18 recites the use of protein material (paragraph [0036] of the specification) in combination with isoflavones treat incontinence. Claims 19 and 20 again recite gender. No new matter has been added, and all amendments are made without prejudice or disclaimer.

#### **Rejection of claim 15 under 35 U.S.C. § 112**

Claim 15 has been rejected under 35 U.S.C. § 112 as being indefinite for the use of the element "soy protein material." Applicant respectfully disagrees. Applicant notes that the term "soy protein material" is properly recited and defined in the specification, and that because the limitation is broad it is not indefinite. Specifically, "soy protein material" is defined as whole soybean seed or protein derivatives that can be formed from whole soybean seed." See, the specification at paragraph [0036]. Further, the term "soy protein material" is well known in the art and has been used in claims in this technical area before. See, for example, U.S. Patent Nos. 6,572,876 and 5,544,566. Finally, as stated in the M.P.E.P § 2173.04 "[b]readth is not indefiniteness." As such, because the term is supported by the specification and understandable to one

of skill in the art, the claim is definite. Thus, Applicant respectfully requests withdrawal of the rejection.

Rejection of claims 1-15 under non-statutory double patenting

Applicant does not own an interest in U.S. Patent No. 6,326,366 to Potter *et al.* (hereinafter, "Potter"), and, therefore, this Application is not subject to terminal disclaimer. As such, the rejection is obviated. To the extent that the reference would operate as a basis for a 35 U.S.C. § 103(a) obviousness rejection, please see the next section.

Rejection of claims 15-19 and 28 under 35 U.S.C. § 102(b)/103(a)

Claims 1-15 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Potter, or, in the alternative, obvious under 35 U.S.C. § 103(a), as discussed *supra*. As an initial matter, Applicant has amended the claims, which are distinguishable and non-obvious for the following reasons.

Applicant teaches a method of treating urinary incontinence for patients that are not menopausal women, unlike Potter. Novelty resides in the fact that urinary incontinence can be treated without exposing the patient to exogenous estrogen, which has many undesirable effects. Potter only teaches treatment of menopausal incontinence which is caused by estrogen deficiency. Non-estrogen deficient patients, such as males or non-menopausal women, could not be treated for incontinence using the methods of Potter because, as described in Potter, the use of exogenous estrogen has undesirable side-effects.

This is particularly true for men and for women that are not estrogen deficient. Applicant overcomes these difficulties by inventing a new method of treating incontinence that can avoid the toxicity and side effects of estrogen treatment that would accompany the methods described in Potter. Further, Applicant identifies the patient population (e.g, men or women not receiving estrogen replacement) that will respond to this treatment, which is absent from the disclosure of Potter. See, Examples 1-8. Applicant has amended the claims to recite that the treatment does not include estrogen, and thus, this novel advantage is highlighted as well as the fact that the population that would benefit from treatment.

Further, there is no teaching or even indication that men or women who do not need estrogen replacement, but still suffer from incontinence would benefit from the claimed methods. Potter only teaches using isoflavones as an estrogen replacement or supplement, but not that isoflavones can act independently of estrogen to prevent or treat incontinence in men or women not receiving estrogen replacement therapy. Without such a teaching, one of skill in the art would not be motivated to select or treat the claimed patient populations using the claimed methods, especially not without some form of concomitant estrogen therapy.

Further, new claims 18-20 are drawn to the use of isoflavone in combination with soy protein material. Potter does not disclose the use of soy protein material and isoflavones to treat incontinence. Thus, the claim is novel and non-obvious in view of Potter, as well. Thus, for all of these reasons, Applicant respectfully requests withdrawal of the rejections and allowance of the


new claims.

Conclusion

For at least the reasons discussed above, Applicant believes that these claims define over the prior art of record and are in proper form for allowance. In accordance, Applicant respectfully requests allowance of pending claims.

If the undersigned can be of assistance to the Examiner in addressing issues to advance the application to allowance, please contact the undersigned at the number set forth below. Applicant submits that the enclosed fee necessary for consideration of this *Amendment and Response to Non-Final Office Action* is sufficient. Nevertheless, the Commissioner is hereby authorized to charge any additionally required fees deemed necessary for consideration of this *Amendment Response to Non-Final Office Action* to Account No. 11-1110.

Respectfully submitted,

  
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